

# Strengthening Behavioral and Social Science in Medical Schools

**RFA Number:** RFA-OD-05-001

## Part I Overview Information

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### Department of Health and Human Services (DHHS)

#### Participating Organizations:

National Institutes of Health (NIH)  
( <http://www.nih.gov> )

#### Components of Participating Organizations

Office of Behavioral and Social Sciences Research (OBSSR)  
( <http://obssr.od.nih.gov> )  
National Center for Complementary and Alternative Medicine (NCCAM)  
( <http://nccam.nih.gov/> )  
National Cancer Institute (NCI)  
( <http://www.nci.nih.gov/> )  
National Heart, Lung, and Blood Institute (NHLBI)  
( <http://www.nhlbi.nih.gov/index.htm> )  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
( <http://www.niams.nih.gov/> )  
National Institute of Child Health and Human Development (NICHD)  
( <http://www.nichd.nih.gov/> )

**Announcement Type:** New

**Catalog of Federal Domestic Assistance Number(s):** 93.213 (NCCAM), 93.393 (NCI), 93.837 (NHLBI), 93.846 (NIAMS), 93.864 (NICHD)

#### Key Dates

Release Date: 10/29/2004  
Letters Of Intent Receipt Date(s): December 10, 2004  
Application Receipt Date(s): January 19, 2005  
Peer Review Date(s): June-July 2005  
Council Review Date(s) : September 2005  
Earliest Anticipated Start Date: September 30, 2005  
Additional Information To Be Available Date (Url Activation Date):  
Expiration Date: January 20, 2005

#### Due Dates for E.O. 12372

Not Applicable

#### Executive Summary

The National Institutes of Health (NIH) invites applications for Career Development Awards (K07s) to support individuals interested in enhancing medical education through behavioral and social sciences content and curricula. This award is intended to support schools of medicine and osteopathy at various stages of involvement in behavioral and social sciences curricula. The programmatic priorities are set to ensure that a diverse set of schools are funded with regard to educational approach, size, and maturity of existing curriculum in the behavioral and social sciences. The participating ICs intend to commit approximately \$1.5 million in Fiscal Year (FY) 2005 to fund approximately five to ten new grants in response to this RFA.

Eligible institutions include those that have a domestic school of medicine or osteopathy. Each institution may submit only one grant application per medical school. Eligible principal investigators (PIs) include those with the skills, knowledge, and resources

necessary to carry out the proposed curriculum development to develop an application for support. The principal investigator should possess the research and training expertise, and leadership and administrative capabilities required to develop, and implement or enhance a curriculum of behavioral and social science for use in medical schools. Further, the PI must have demonstrated a commitment to medical education for students and have a regular appointment (i.e., not adjunct) at the rank of associate or full professor in the medical or osteopathic school.

Telecommunications for the hearing impaired: TTY 301-452-0088.

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# Part II - Full Text of Announcement

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## Section I. Funding Opportunity Description

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### 1. Research Objectives

The National Institutes of Health (NIH) invites applications for Career Development Awards (K07s) to support individuals interested in enhancing medical education through behavioral and social sciences content and curricula.

This RFA has three important objectives. The first objective of the Curriculum Development Award in Behavioral and Social Sciences in Medical Schools is the development of enhanced courses, curricula and education designed to increase medical students' knowledge and skills in the behavioral and social sciences related to health. Secondary targets of these curricula include physicians in training, faculty, other researchers, and practicing physicians. The second objective is to provide curriculum and other products for dissemination to other medical schools as well as other health care professional schools. The third objective is to foster health-related research and careers in behavioral and social science within medical school settings. This latter objective is to catalyze further development of behavioral and social sciences in schools of medicine and osteopathy in order to advance the health of the nation.

This award is intended to support schools of medicine and osteopathy at various stages of involvement in behavioral and social sciences curricula. The programmatic priorities are set to ensure that a diverse set of schools are funded with regard to educational approach, size, and maturity of existing curriculum in the behavioral and social sciences.

This RFA was strongly influenced by a recent Institute of Medicine (IOM) study: *Improving Medical Education: Enhancing the Behavioral and Social Science Content of Medical School Curricula* which was in part supported by the NIH. In its recent report, the Institute of Medicine reached an overarching conclusion: "No physician's education would be complete without an understanding of the role played by behavioral and social factors in human health and disease, knowledge of the ways in which these factors can be modified, and an appreciation of how personal life experiences influence physician-patient relationships." P. 60 The following training objectives will enhance the social and behavioral science content of the educational programs in medical schools; examples not inclusive:

- o Developing high quality medical school curricula in the six domains identified by the IOM report (Chapter 3):

- Mind-Body interactions in health and disease: Psychology, biological, social and behavioral factors and influences on health and disease
- Patient Behavior: Health promoting and health damaging behaviors, principles of behavior change, influences on health behavior patterns
- Physician role and behavior: Understanding of physician beliefs, behaviors and values on patient care, physician self-care, and Physician-patient interactions
- Physician-patient interactions: Communication and decision-making, managing difficult interactions
- Social and cultural issues in health care: Social determinants of health outcomes, role of complementary and alternative medicine
- Health policy and economics: Economic factors influencing health behaviors and patient care

- o The development of educational curricula and relevant experiences spanning the entire duration of the medical school experience (not restricted to just pre-clinical years).

- o The development of competencies that will significantly increase the knowledge and skills of medical students, physicians in training, faculty, and practicing physicians. These competencies will promote the understanding of the role of psychological, social, cultural, and economic factors in health and illness, and develop clinical competencies in medical interviews, communication, counseling, behavioral management, and behavioral interventions.

- o The promotion of research studies in behavioral and social sciences at the awardee's institution, funded by other support. Increasing research and clinical activities require an integrative approach across traditional disciplinary and professional boundaries. This requires skilled physicians working cooperatively in research and clinical teams. The NIH is interested in the educational experiences that encourage the integration of traditional biomedical and clinical sciences with the behavioral and social science disciplines, and other non-conventional disciplines, such as complementary and alternative approaches to health care.

- o The promotion of the professional development of the awardee so s/he can serve as a focal point for multidisciplinary interactions promoting integration of behavioral and social sciences into the approaches, teaching, research, clinical care, and training of other health care professionals.

- o The development or enhancement of an infrastructure at the awardee's institution to continue educational and training programs when the award is concluded. The program may include the six domains, clinical competencies, and other relevant topics areas within behavioral and social sciences.

o Through collaboration with other awardees and their institutions, develop strategies, curricula, and training modules that can be adapted and used by other academic training units and institutions.

o Evaluate the impact of the proposed program.

## Section II. Award Information

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### 1. Mechanism(s) of Support

This funding opportunity will use the NIH K07 award mechanism(s). As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses the just-in-time budget concepts. It also uses the non-modular budget format described in the PHS 398 application instructions. Specifically a detailed categorical budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application.

### 2. Funds Available

The participating ICs intend to commit approximately \$1.5 million dollars in FY 05 to fund five to ten new and/or competitive continuation grants in response to this RFA. An applicant may request a project period of up to five years and a budget for direct costs up to \$250,000 per year. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the ICs provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

## Section III. Eligibility Information

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### 1. Eligible Applicants

#### 1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Domestic institutions/organizations
- Foreign institutions are not eligible to apply
- Faith-based or community-based organizations

You may submit an application if your institution has a domestic school of medicine or osteopathy. Each institution may submit only one grant application per school of medicine or osteopathy.

#### 1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

Principal Investigators (PI) should possess the research and training expertise, and leadership and administrative capabilities required to develop, and implement or enhance a curriculum of behavioral and social science for use in medical schools. The PI should have demonstrated a commitment to medical education for students. PI must have a regular appointment (i.e., not adjunct) at the rank of associate or full professor at the medical or osteopathic school. The PI must devote 25-50% of his/her full-time professional effort on course(s) and curriculum development for the period of the award. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs. Principal Investigators must be U.S. citizens or non-citizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Card or some other verification of legal admission as a permanent resident.

## 2. Cost Sharing

Cost sharing is not required ([http://grants.nih.gov/grants/policy/nihgps\\_2003/nihgps\\_Part2.htm#matching\\_or\\_cost\\_sharing](http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_Part2.htm#matching_or_cost_sharing))

## 3. Other-Special Eligibility Criteria

**Program:** The Principal Investigator is expected to develop courses or curricula and educational experiences that address the six general domains of behavioral and social science knowledge identified in the Institute of Medicine report and listed above: mind-body interactions in health and disease, patient behavior, physician role and behavior, patient interactions, social and cultural issues, and finally health policy and economics. The applicant may offer an alternative approach based on their scientific knowledge and expertise and may expand beyond the six general domains to include other relevant domains by providing a justification. The curricula may be organized around an interdisciplinary theme that provides a framework for merging concepts and approaches from multiple disciplines into an integrated course/curriculum. These efforts should also encourage collaboration and interaction across behavioral-social science faculty and biomedical or clinical faculty. Educational approaches and materials should be designed to enable dissemination and adoption by other medical or osteopathy schools and illustrate models for consideration by schools of other health professionals.

**Environment:** The institution must demonstrate a commitment to the further development and implementation of these courses and curricula following the award. The institution must provide assurance that the Principal Investigator is an integral part of its research and academic programs, and demonstrate a sufficient research base in behavioral and social sciences related to health to refine and advance knowledge in this field.

**Allowable costs:**

**Salary:** This award will provide salary and fringe benefits for the Principal Investigator for levels of effort between 25 and 50 percent. The total salary requested must be based on the Principal Investigator's full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure. The salary will always be pro-rated for the percentage of time/effort of a full-time position, based on the institutional salary scales, keeping the DHHS salary cap as a maximum for which the amount is determined.

The institution may supplement this award contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. In no case may DHHS funds be used for salary supplementation. Institutional supplementation of salary must not require duties or responsibilities that would interfere with the purpose of the Curriculum Development Award.

Salary support may be requested for other collaborating faculty members.

**Annual principal investigator meeting with NIH personnel:** The applicant should budget for one annual trip to NIH for an investigator's meeting.

**Research Support:** A maximum of \$50,000 per year may be requested for ancillary needs, such as collaborators, consultants, equipment, computer time, etc. All requests for ancillary support must be justified. In no case will the allowance provided exceed \$50,000. Salaries for mentors or for secretarial, technical and/or administrative assistance are not allowed.

**Facilities and Administrative (F&A) Costs:** F&A costs will be reimbursed at 8 percent of modified total direct costs, or at the actual indirect cost rate, whichever is less.

## Section IV. Application and Submission Information

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### 1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Telecommunications for the hearing impaired: TTY 301-451-0088.

## 2. Content and Form of Application Submission

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

See Section VI.2 Administrative Requirements for additional information.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

## 3. Submission Dates

Applications must be received on or before the Application Receipt Date listed below.

### 3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date: December 10, 2004  
Application Receipt Date(s): January 19, 2005  
Peer Review Date: June-July 2005  
Council Review Date: September 2005  
Earliest Anticipated Start Date: September 30, 2005

#### 3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Dr. Lynn Nielsen-Bohlman  
Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive  
Room 3089F, MSC 7848  
Bethesda, MD 20892-7848 (20817 for express/courier delivery)  
Telephone: (301) 594-5287  
FAX: (301) 480-1056  
Email: [NielsenL@csr.nih.gov](mailto:NielsenL@csr.nih.gov)

### 3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, five signed photocopies, and all copied of the appendix material in one package to:

Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive, Room 1040, MSC 7710

Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)  
Bethesda, MD 20817 (for express/courier service; non-USPS service)

**Using the RFA Label:** The RFA label available in the PHS 398 application instructions must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

### 3.C. Application Processing

Applications must be received **on or before the application receipt date** listed in the heading of this funding opportunity. If an application is received after that date, it will be returned to the applicant without review. Applications will be evaluated for completeness by CSR.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

## 4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

## 5. Funding Restrictions

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>. (See also Section VI.3. Award Criteria)

## 6. Other Submission Requirements

The application must address the following issues:

Principal Investigator:

Describe the Principal Investigator's commitment to developing and implementing a course(s) or curricula, which meet the scientific and educational requirements of the behavioral and social science content in medical school education. Provide evidence that the Principal Investigator has the capacity to develop and implement course(s) or curricula that are based on sound research concepts and educational principles.

Course or Curriculum Development Plan:

Describe the plan and how it fits into the institutional plans and goals. Explain how this curriculum is distinguished from other curricula within the existing educational infrastructure and framework of the applicant institution. Describe the immediate and long-term objectives of the award and how those objectives will meet the needs for expansion or enhancement of the academic or research capacity of the institution in the behavioral and social science content of medical school curricula.

Environment and Institutional Commitment:

The institution must provide evidence of commitment and support for the proposed program. There must be evidence of support for the Principal Investigator and his/her course and/or curricula development and implementation plans and for the further enhancement of the behavioral and social science area. The institution should demonstrate a commitment in sustaining the support beyond the funding period.



#### Collaborator's Statement:

Principal Investigators must include information about any collaborator(s) including her/his research and training qualifications. The application must also include information describing the nature and extent of collaboration that will occur during the proposed award period.

#### Budget:

Budget requests must be provided according to the instructions in form PHS 398. The request for ancillary support, i.e., essential books, travel, consultants, equipment, computer time, etc., must be justified and specified by category.

## Plan for Sharing Research Data

A plan for sharing research data is not required.

## Sharing Research Resources

Not applicable to this announcement.

## Section V. Application Review Information

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### 1. Criteria

Only the review criteria described below will be considered in the review process.

### 2. Review and Selection Process

Upon receipt, applications will be reviewed for completeness by the CSR and for responsiveness by OBSSR . Incomplete and/or non-responsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the participating ICs in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique
- Receive a second level of review by the appropriate national advisory councils or boards.

### 3. Merit Review Criteria

Applications submitted in response to a funding opportunity will compete for available funds with all other recommended applications.

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application.

**Investigator :** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

- Evidence of the Principal Investigator's excellence in research and academic activities, and the quality and breadth of prior scientific training experience.



- Commitment to developing and implementing academic course(s) or curricula which meet the scientific and educational requirements of enhancing the behavioral and social science content of medical school curricula.
- Identification of appropriate collaborator(s) from the relevant biomedical and clinical disciplines who will agree to collaborate on the development of the course(s) and curricula.
- Evidence of the capacity to develop and implement course(s) or curricula that are based on sound research concepts and educational principles.
- Evidence of potential to become a leader in developing educational behavioral and social science scientific programs at the institution(s).
- Evidence of support from the Dean and appropriate departmental chair persons of the institution.

**Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

- Long term commitment of the institution to strengthening behavioral and social science research and education activities in areas of interest to the NIH beyond the funding period. For example, an institutional commitment to revise several courses or develop several new courses would be regarded as compelling evidence of institutional support.
- Merit of the institution's plan to strengthen and incorporate behavioral and social science topics into the curriculum through the entire length of medical education, including residency.
- Scope and nature of collaboration among participating departments.

#### **Course/Curricula Development Plan:**

- Quality, feasibility and innovation of course and curricula development and implementation plans for enhancing the behavioral and social science content of medical school curricula throughout the entire length (preclinical and clinical components) of medical school education.
- Appropriateness of the plan to the goals of this program. Adequacy of the justification provided for the need for the proposed curriculum relative to other on-going education and/or training activities being currently sponsored within the school.
- Immediate and long-term objectives of the award and how those objectives will meet the needs for expansion or enhancement of the academic or research capacity of the institution in the behavioral and social science area.
- Quality of plan to disseminate the materials nationwide.

### **3.A. Additional Review Criteria:**

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

**Protection of Human Subjects from Research Risk:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

**Inclusion of Women, Minorities and Children in Research:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

**Care and Use of Vertebrate Animals in Research:** If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

### **3.B. Additional Review Considerations**

**Budget:** The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

### **3.C. Sharing Research Data**

A data sharing plan is not required.

### **3.D. Sharing Research Resources**

Not applicable to this announcement.

## Section VI. Award Administration Information

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### 1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a summary statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPs\\_part4.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_part4.htm)

A formal notification in the form of a Notice of award will be provided to the applicant organization. The notice of award signed by the grants management officer is the authorizing document.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA (Notice of Grant Award) are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

The NGA will be submitted via e-mail.

### 2. Administrative Requirements

All NIH Grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPs\\_Part4.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPs\\_part9.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_part9.htm).

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

### 3. Award Criteria

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

### 4. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually: <http://grants.nih.gov/grants/funding/2590/2590.htm> and financial statements as required in the NIH Grants Policy Statement.

## Section VII. Agency Contacts

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We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

### 1. Scientific/Research Contacts:

Ronald Abeles, Ph.D.

Office of Behavioral and Social Sciences Research  
Office of the Director  
Gateway Building, Suite 2C-234  
7201 Wisconsin Avenue  
Bethesda, MD 20892  
Telephone: (301) 496-7859  
FAX: (301) 301-435-8779  
Email: [abeles@nih.gov](mailto:abeles@nih.gov)

Jeffrey Evans, Ph.D.  
Demographic and Behavioral Sciences Branch  
National Institute of Child Health and Human Development  
6100 Executive Boulevard , 8B07, MSC 7510  
Bethesda , MD 20892  
Telephone: (301) 496-1174  
FAX: (301) 496-0962  
Email: [evansvj@nih.gov](mailto:evansvj@nih.gov)

Catherine M. Stoney, Ph.D.  
National Center for Complementary and Alternative Medicine  
National Institutes of Health  
6707 Democracy Blvd. , Room 401  
Bethesda , MD 20892  
Telephone: (301) 402-1272  
FAX: (301) 480-3621  
Email: [stoneyc@mail.nih.gov](mailto:stoneyc@mail.nih.gov)

Michael Stefanek , Ph.D.  
Chief, Basic Biobehavioral Research Branch  
Behavioral Research Branch  
Division of Cancer Control and Population Sciences  
National Cancer Institute  
6130 Executive Blvd. , EPN 4066  
Bethesda, MD 20892  
Telephone: (301) 496-8776  
FAX: (301) 594-6787  
Email: [Ms496r@nih.gov](mailto:Ms496r@nih.gov)

Jared Jobe , Ph.D.  
Health Scientist Administrator  
Behavioral Medicine Scientific Research Group  
Division of Epidemiology and Clinical Applications  
National Heart, Lung, and Blood Institute  
6701 Rockledge Drive, Room 8120  
Bethesda, MD 20892-7936  
Telephone: (301) 435-0407  
FAX: (301) 480-1773  
Email: [jobej@nhlbi.nih.gov](mailto:jobej@nhlbi.nih.gov)

Deborah N. Ader, Ph.D.  
Director, Behavioral and Prevention Research Program  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
6701 Democracy Blvd., Suite 800  
Bethesda, MD 20892  
Telephone: (301) 594-5032  
FAX: (301) 480-4543  
Email: [Aderd@mail.nih.gov](mailto:Aderd@mail.nih.gov)

## 2. Peer Review Contacts:

Dr. Lynn Nielsen-Bohlman  
Center for Scientific Review  
National Institutes of Health

6701 Rockledge Drive  
Room 3089F, MSC 7848  
Bethesda , MD 20892-7848 (20817 for express/courier delivery)  
Telephone: (301) 594-5287  
FAX: (301) 480-1056  
Email: [NielsenL@csr.nih.gov](mailto:NielsenL@csr.nih.gov)

### 3. Financial or Grants Management Contacts:

Victoria P. Connors  
Grants Management Team Leader  
National Institute of Child Health and Human Development  
National Institutes of Health  
6100 Executive Blvd.  
Room 8A17P, MSC 7510  
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## Section VIII. Other Information

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## Required Federal Citations

### Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.

### Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

### Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at

<http://grants.nih.gov/grants/funding/children/children.htm>.

### Required Education on The Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

### Public Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm). Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

### Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

### URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise

specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

**Healthy People 2010:**

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

**Authority and Regulations:**

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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